REMARKS:

In response to the Office Action mailed April 25, 2008, claims 1 and 25 have been amended. Support for the amendments may be found in the specification, e.g., at page 55, lines 1-10. No new matter has been introduced. Claims 1-10 and 21-30 remain pending.

In the Office Action, claims 1, 6-7, 25, and 28-30 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,045,570 ("the Epstein reference") in view of U.S. Publication No. 2002/ 0193808 ("the Belef reference"), claims 2-5 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Epstein reference in view of the Belef reference and further in view of U.S. Patent No. 5,626,601 ("the Gershony reference"), claims 8-10 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Epstein reference in view of the Belef reference and further in view of U.S. Patent No. 6,562,059 ("the Edwards reference"), claims 21-23 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Gershony reference, claim 24 was rejected under 35 U.S.C. § 103(a) as unpatentable over the Gershony reference in view of the Belef reference, and claims 26-27 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Epstein reference in view of the Belef reference and further in view of U.S. Patent No. 6,162,240 ("the Cates reference"). Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the Epstein reference, a closure device 21 is disclosed that includes a tubular member 22 including a main lumen 26 and a second lumen 27 communicating with a port 28 on the distal extremity 24. Col. 4, line 66 to col. 5, line 13. A closure assembly 32 is carried by the distal extremity 24 of the tubular member 22 and is coupled to a deployment mechanism

33 for movement from a contracted to an expanded position. Col. 5, lines 28-33. The deployment mechanism 33 includes a push-pull wire 41 extending from the closure assembly 32 out the proximal extremity 23 of the tubular member 22 and connected to a handle assembly 44. Col. 5, line 65 to col. 6, line 10. The handle 44 is formed of a body 46 that is mounted on the proximal extremity 23 of the tubular member 22. Col. 6, lines 11-14. A button 47 is provided on the handle 44 that is slidably mounted in a slot 49 for moving the closure assembly 32 between the contracted and expanded positions. Col. 6, lines 14-24. Thus, the handle 44 does not include a piston slidably disposed within a chamber nor a reservoir filled with inflation media. Instead, the device merely includes a push-pull wire arrangement that moves the closure assembly 32 from the contracted to the expanded position.

The Epstein closure device 21 also includes biological sealant means 81 carried by the handle 44 and in communication with the second lumen 27 for delivering sealant components via the external port 28. Col. 7, lines 1215; col. 6, lines 28-43. During use, the closure device 21 is inserted into a sheath 111 in a puncture 106 extending to a vessel lumen 104 with the closure assembly 32 in the retracted position. Col. 9, lines 6-10; FIG. 5A. Once the distal extremity 24 of the tubular member 22 is exposed in the lumen 104, the sheath 111 is withdrawn, and the button 47 is retracted to expand the closure assembly 32. Col. 9, lines 10-23, 36-44. The tubular member 22 is then retracted ***with the closure assembly 32*** until the closure assembly 32 contacts the vessel wall 103 to form a seal. Col. 9, lines 54-60; FIG. 5B. A sealant 116 is then delivered through the second lumen 27 of the tubular member 22 and "through the exit port 28 which is adjacent the closure assembly 32." Col. 10, lines 35-44; FIG. 5C. The tubular member 22 is not

movable relative to the closure assembly 32, because it is fixed to the handle 44, which also prevents movement of the closure assembly 32 once expanded.

Once the sealant has assumed the desired state, the button 47 is moved within the slot 49 to retract the closure assembly 32 back into the tubular member 22, and the closure device 21 is removed from the puncture 106. Col. 11, lines 3-16. Thus, the Epstein reference does not teach or suggest a tubular member that is retractable proximally relative to an occlusion member. In contrast, the Epstein reference discloses a tubular member that remains fixed relative to a closure assembly, which is necessary because the tubular member is used to manipulate the closure assembly within a puncture and lumen.

Turning to the present claims, claim 1 recites an apparatus for sealing a puncture extending through tissue that includes a tubular member having a proximal end, a distal end sized for insertion into the puncture, and a lumen extending between the proximal and distal ends; an elongate occlusion member slidably disposed within the tubular member, the occlusion member comprising a proximal end, and a distal end extending distally through an opening in the distal end of the tubular member; an expandable member on the occlusion member distal end; a delivery device coupled to the proximal end of the tubular member, the delivery device comprising a plunger that is advanceable to deliver a sealing compound into the tubular member lumen; and a retraction assembly coupled to the proximal end of the tubular member and to the occlusion member, the retraction assembly comprising a lock for securing the tubular member in a distal position relative to the occlusion member, and a trigger that is activated by advancement of the plunger to thereby disengage the lock, the retraction assembly being biased to retract the tubular member proximally relative to the occlusion member when the lock is disengaged.

The Epstein reference fails to disclose, teach, or suggest anything about a retraction assembly, as conceded in the first paragraph on page 3 of the Office Action. Even more importantly, however, the Epstein reference teaches against a retraction assembly that retracts a tubular member proximally relative to an occlusion member (let alone one that is biased to retract), because the tubular member 22 of the Epstein reference is necessarily coupled to the closure assembly 32, as explained above.

Turning to the Belef reference, an apparatus 10 is disclosed for delivering a clip 5 that includes a carrier assembly 14 for carrying the clip 5 and an actuator assembly 16. FIGS. 1, 2; ¶ [0039]. The actuator assembly 16 includes an obturator assembly 18 including an expandable distal portion 182. FIGS. 10A, 10B, ¶¶ [0072], [0073]. When the apparatus 10 is activated to deliver the clip 5, the splines 186 of the distal portion 182 are automatically returned to their collapsed configuration and retracted into sheath 12 as the clip 5 is advanced ***over*** the sheath 12. See FIGS. 12G-12I, ¶ [0099].

First, the Belef reference does not teach or suggest a tubular member having a lumen, and a delivery device coupled to the proximal end of the tubular member, the delivery device comprising a plunger that is advanceable to deliver a sealing compound ***from the tubular member lumen out the distal end of the tubular member***, as recited in claim 1. Instead, the Belef reference discloses an apparatus that delivers a clip 5 along the ***outside*** of both a sheath 12 and an obturator assembly 18.

Further, the Belef reference operates in a directly opposite manner to the retraction assembly recited in claim 1. Claim 1 recites that the retraction assembly is biased to ***retract the tubular member proximally relative to the occlusion member*** when the lock is disengaged while

delivering the sealing compound from the tubular member lumen out the distal end of the tubular member. In direct contrast, the Belef reference discloses retracting the obturator assembly 18 (which is the only component that could arguably constitute an occlusion member as recited in claim 1) into a sheath 12. Thus, the Belef reference actually advances a tubular member relative to an occlusion member, unlike the retraction assembly of claim 1.

Finally, the Belef carrier assembly 14 cannot constitute the recited occlusion member since it does not include an expandable member on its distal end. Instead, the clip 5 is disposed at the distal end of the carrier assembly 14, since the carrier assembly necessarily carries the clip down the sheath 12 over the obturator assembly 18.

For these reasons, even if the Belef reference could somehow be properly combined with the Epstein reference, the result would be the opposite of the apparatus of claim 1. However, the Epstein and Belef references cannot be properly combined with one another, because, if the Epstein closure assembly 32 were retracted when sealant components are delivered (similar to the Belef apparatus), the sealant components would simply pass through the puncture and enter the blood vessel. This would create substantial risk of embolism or other harm to the patient. Thus, a person of ordinary skill would recognize that such automatic retraction during sealant delivery would clearly be undesirable and, in fact, dangerous to the patient.

For these reasons, claim 1 and its dependent claims are not obvious over the Epstein and Belef references. For similar reasons, claim 25 and its dependent claims are also not obvious over the Epstein and Belef reference.

The Cates reference cannot be properly combined with the other cited references and, even if somehow properly combined, fails to disclose, teach, or suggest the features wholly

absent from the other cited references, as explained in Applicants' previous response. Finally, the Edwards reference also fails to provide any additional teaching or suggestion absent from the other cited references to render claims 1 and 25 and their dependent claims obvious.

Turning to the rejections based on the Gershony reference, the Gershony reference fails to disclose, teach, or suggest the features of claim 21. Specifically, the Gershony reference does not disclose, teach, or suggest anything about a housing on the proximal end of an outer member, the housing comprising a chamber in fluid communication with the inflation lumen, a piston slidably disposed within the chamber and coupled to the inner member, a reservoir filled with inflation media and in fluid communication with the chamber, and an actuator that may be activated by a user to direct the inflation media from the reservoir into the chamber and inflation lumen, thereby substantially simultaneously expanding the expandable member and directing the piston proximally to thereby pull the inner member proximally to shorten the expandable member as it expands.

Instead, the Gershony reference merely discloses a vascular sealing device 10 that includes a core wire 17 that may be manually proximally pulled to flatten a balloon 15. Col. 5, lines 41-62. Such manual manipulation introduces risk of user error unlike the apparatus recited in claim 25. Thus, the claimed apparatus provides new and nonobvious advantages over the Gershony apparatus.

Finally, none of the cited references discloses, teaches, or suggests anything about a housing including a piston and reservoir that operates to substantially simultaneously expand an expandable member and shorten the expandable member as it expands. The Office Action's cursory statement that such an apparatus would be obvious fails to present a prima facie case of

obviousness. Accordingly, for these reasons, claim 21 and its dependent claims are not obvious over the Gershony reference, either alone or if somehow combined with the other cited references.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

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